Office of Civilian Radioactive Waste Management QA: QA

AUGMENTED QUALITY ASSURANCE PROGRAM (AQAP)

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TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

INTRODUCTION

The purpose of the Augmented Quality Assurance Program (hereafter referred to as the AQAP) is to describe the applicability and requirements of the Quality Assurance (QA) program that are applied to ensure that Office of Repository Development (ORD) products and services meet or exceed customer expectations. Accordingly, the AQAP is the QA program that addresses the quality of work performed by or for ORD, including items and activities related to: fire protection; radiation protection; the design and construction of non-nuclear facilities; normal operations of the nuclear facility; environmental compliance; occupational safety; and the work required to implement the ORD Integrated Safety Management program. The Integrated Safety Management identifies the development of a culture that addresses balanced priorities focusing on the safety of workers, the public, and the recognition of hazards and their mitigation to ensure a safe environment. A management system is in place (DOE/RW-0523, *Integrated Safety Management Plan*) that supports the principles and functions of DOE P 450.4, *Safety Management System Policy.*

The AQAP is developed and maintained through a process that selectively applies the varied QA program criteria, using a graded QA approach. This process provides due consideration to the extent and the applicability of source requirements, available guidance, and the current foreseeable activities expected to be performed by or for ORD. ORD reviews, evaluates, and improves its overall performance using rigorous assessment processes based on this AQAP.

The AQAP identifies requirements that are necessary for the development of an effective QA program. The integration of the various quality assurance programs and activities are described in the *Quality Assurance Management Policy.* The *Quality Assurance Management Policy* describes how the various individual quality assurance programs are integrated together to formulate the overall Office of Civilian Radioactive Waste Management QA program.

Throughout the AQAP, the terms "should" and "shall" are used. "Should" is used to indicate a suggestion or a good practice. "Shall" is used to denote a mandatory practice or a requirement. The word "must" is also used and also means mandatory. The term "are" is used in an explanatory sense. The use of the term "safety" in the AQAP refers to safety considerations, other than those safety considerations defined in 10 CFR 63. The term "item" is a collective term that may be used in place of: appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support system.

ORD, the Civilian Radioactive Waste Management System Management and Operating Contractor, and other organizations, while conducting activities or providing items or services that affect or may affect safety (items and activities not governed by 10 CFR 63) at Yucca Mountain facilities, must conduct work in accordance with 10 CFR 830, Subpart A and this AQAP.

The requirements in this AQAP are based on the principle that work should be planned, documented, performed under controlled conditions, and periodically assessed to establish work item quality and process effectiveness and to promote improvement through rigorous assessment

and corrective action. Managers are responsible for activities that are needed to achieve quality and to promote continuous improvement, including: planning, organizing, controlling, directing, and supporting self-assessing and self-identifying conditions adverse to quality.

Line organizations achieve and maintain quality to minimize environmental, safety, and health risks and impacts while maximizing reliability and performance. The Office of Quality Assurance and other organizations perform independent assessments of items and activities, as necessary, to verify the achievement of quality. This AQAP further delineates the quality contributions expected of personnel.

1.0 MANAGEMENT REQUIREMENTS

The fundamental elements related to the organization and management of the Office of Repository Development (ORD) Augmented Quality Assurance Program (AQAP), as well as the fundamentals to be applied to the function and application of U.S. Department of Energy (DOE) contract administration related to the items and activities governed by this AQAP are described in the following subsections.

1.1 ORGANIZATION AND QUALITY ASSURANCE PROGRAM

This subsection describes the requirement for the organizational structure, functional responsibilities, levels of authority, and interfaces for those personnel who manage, perform, and assess work and activities that are required to implement the AQAP.
Effective implementation of the AQAP is dependent on the efforts at all levels. The organization should be structured such that the individual performing the work is responsible for achieving and maintaining quality. Managers are responsible for defining quality, developing appropriate plans to attain quality, supporting the workers in pursuit of quality, and evaluating quality achievement and improvement. Line managers are responsible for defining, integrating, and ensuring effective implementation of the AQAP.

1.1.1 Management Roles and Responsibilities include:

A. The Director, Office of Civilian Radioactive Waste Management (OCRWM) is responsible for the overall implementation of DOE programs, policies, orders, and guidance. As such, the Director, OCRWM provides policy direction and oversight of activities that affect implementation of the Quality Assurance (QA) program.

B. The overall responsibility for the implementation of the AQAP has been delegated to the Deputy Director, ORD.

1. The Deputy Director, ORD reports directly to the Director, OCRWM and has overall responsibility for the design and construction of the geologic repository, including management oversight and support of the day-to-day operation of the Yucca Mountain Project (YMP). This is the senior executive position responsible for setting and implementing policies, objectives, expectations, and priorities to ensure YMP activities are performed in accordance with the QA Program.

2. Specific duties and overall responsibilities of the Deputy Director, ORD include:

   a. Directing ORD staff related activities

   b. Developing, organizing, and maintaining control and oversight activities related to the technical and quality functions of the principal contractors and ORD suppliers in their support of the YMP

   c. Developing the overall plans and schedules for licensing, design, procurement, construction, and testing activities

   d. Developing and implementing technical and administrative controls to ensure that quality objectives are met

   e. Directing, coordinating, and reviewing principal contractor activities including design, procurement, license application preparation, and on-site construction testing activities

   f. Reviewing and accepting contract required quality-related deliverables submitted by principal contractors and suppliers.

3. The Deputy Director, ORD has delegated the following functions to direct report organizations. These individuals may report through an additional layer of management, but shall retain sufficient authority and organizational freedom to implement their assigned responsibilities. The assigned individuals may be responsible for activities at a single or at multiple locations and may fulfill more than one function. Separate managers may also fulfill the different aspects of the same responsibilities. Delegations include:

   a. The management position responsible for developing the License Application; the regulatory strategy regarding U.S. Nuclear Regulatory Commission licensing, the U.S. Nuclear Regulatory Commission interactions, the post-closure performance assessment, and the performance confirmation.

   b. The management position responsible for site operations and the site support infrastructure is responsible for ensuring that site construction and operation activities comply with applicable federal, state, local, and Indian tribe statutes; for constructing facilities and structures associated with the geologic repository, including the underground construction of the Exploratory Studies Facility and drilling operations; and for integrating field operations including engineering, design, construction, and site testing activities.

c. The management position responsible for managing procurement related activities and the ORD federal employee training program; overseeing contractor training programs; verifying the education and experience of applicable ORD employees; and for overseeing the records management system.

d. The management position responsible for establishing the requirements for the repository design; monitoring principal contractor design activities; providing overall direction and approving the basis for placement of items on the "Q List"; and for performing pre-closure safety analysis and post-closure analysis on barriers important to waste isolation.

e. The management position responsible for coordinating the development of ORD procedures, overseeing principal contractor document development and the document control system; developing and overseeing the ORD document hierarchy and the document management system; identifying, disseminating, and maintaining ORD programmatic requirements; managing and overseeing the OCRWM corrective action program activities, and trending conditions adverse to quality.

f. The management position responsible for the execution of the QA function and verification of effective implementation of the AQAP.

C. General and Management Specific Responsibilities include:

1. ORD managers establish and cultivate principles and practices that integrate QA program requirements and performance standards within the ORD structure and control systems.

2. ORD managers are also responsible for ensuring that those personnel who are assigned work have the proper qualifications, training, resources, oversight, and support to achieve ORD objectives.

3. ORD managers provide planning, organization, direction, control, and support to achieve ORD objectives.

4. ORD directors are responsible for planning, organizing, directing, controlling, and evaluating those activities in their area of responsibility that support the ORD mission. Responsibilities include, but are not limited to:

   a. Ensuring compliance with applicable regulations, DOE orders, applicable state and local laws, and other requirements that apply to ORD programs

   b. Developing, implementing, and maintaining plans, policies, and procedures

c. Ensuring that adequate technical and QA training is provided for personnel performing activities governed by the AQAP

d. Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records

e. Identifying, investigating, reporting, and correcting quality problems

f. Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, health, or quality considerations.

5. Line managers are responsible for achieving quality and for minimizing environmental, safety, and health risks and impacts while maximizing safety, reliability, and performance.

6. Managers should establish communication channels that provide timely, routine, and wide dissemination of information pertinent to quality performance.

7. Managers are responsible for defining quality, developing appropriate plans to attain quality, providing support for the workers in pursuit of quality, and evaluating quality achievement.

8. Effective implementation of the AQAP is dependent on efforts at all levels. The ORD organization is structured such that the individual performing the work is responsible for achieving and maintaining quality.

9. Where more than one ORD organization is involved in the execution of activities covered by the AQAP, the responsibility and authority of each organization shall be clearly established and documented. The internal interfaces between organizational units are depicted in ORD organizational charts. Specific interactions between DOE elements are described in implementing documents.

D. Personnel Assigned to Perform ORD Activities:

1. ORD organizations define, achieve, and evaluate quality; recommend and promote improvements in the quality of items and processes; and identify, document, and resolve problems. It is the responsibility of personnel, including contractor personnel, assigned to perform ORD activities to:

a. Work to applicable approved ORD procedures
b. Be responsible for the quality of his or her work
c. Identify problems and recommend improvements.

1.1.2 Employees

Each employee is responsible for the quality of his or her work and for promptly reporting existing, developing, or potential adverse conditions to the responsible management or through other avenues for evaluation and action in accordance with Subsection 1.4, Quality Improvement, of this AQAP.

1.1.3 Communication and Interface Responsibilities

A. Communication Responsibilities:

Management should establish communication channels that provide timely and wide dissemination of information pertinent to quality performance.

B. Interface Responsibilities:

Where more than one group is involved in the execution of activities covered by this AQAP, the responsibility, the levels of authority, and the interfaces of each group need to be established and documented. The external interfaces between organizations, the internal interfaces between units, and any interface changes also need to be documented.

1.2 IMPLEMENTATION OF THE AQAP

1.2.1 Quality Assurance Program Documents

Responsible ORD organizations shall develop and follow plans and procedures that are needed to effectively implement the AQAP requirements.

ORD personnel must meet applicable AQAP requirements when performing their work. Assigned personnel provide oversight of activities, performs reviews, conducts management and independent assessments, and utilizes the Corrective Action Program to document, correct, and track deficiencies and other conditions.

1.2.2 Applicability of AQAP Requirements

The provisions of this AQAP apply to items and activities performed by the Office of Repository Development, the Civilian Radioactive Waste Management System Management and Operating Contractor, the U.S. Geological Survey, national laboratories, and OCRWM direct-support contractors while performing work in support of ORD that is not governed by 10 CFR 63, Subpart G.

1.2.3 QA Grading of Items and Activities and Applying Management Controls

A. The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality and safety of the item or activity.

B. The graded approach is the process by which the scope, depth, and rigor of analysis, documentation, verification, and the other controls necessary to comply with AQAP requirements are developed for a specific item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility or activity. The graded approach should be used to determine the appropriate level of controls necessary to manage items, systems, and activities and should be commensurate with the following factors:

1. The importance of the item or activity with respect to safety, costs, schedule, and regulatory compliance (if suitable evaluations have been performed for other purposes, there is no requirement to re-evaluate)
2. The need to demonstrate compliance with specific regulatory design and QA requirements
3. The impact on the results of performance assessments and engineering analyses
4. The magnitude of any potential hazard or the consequences of failure
5. The life-cycle stage of the facility or item
6. The programmatic mission of the facility
7. The particular characteristics of the facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls or processes)
8. The relative importance to radiological and non-radiological hazards.

C. Grading methods for each organization shall provide for:

1. The assignment of management and quality assurance controls
2. The criteria used to select the quality controls
3. Documentation of the basis, the logic and the method of implementation for grading in the quality management system
4. Periodic review in light of changes that may have occurred and, if appropriate, revision of the grading methods and levels to reflect the changes.

Note: The grading process is not to be used to obtain exemptions from requirements.

1.2.4 Planning Work

Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. Work must be performed to the established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.

1.3 PERSONNEL QUALIFICATION AND TRAINING

Personnel shall be capable of performing their assigned tasks and shall receive any needed training to ensure that their job proficiency is maintained. Before personnel are allowed to work independently, managers shall ensure that they have the necessary experience, knowledge, skills, and abilities to perform their assigned tasks.

Managers shall commit resources to train, qualify, and maintain personnel capability and proficiency.

Procedures, policies, and instructions that describe personnel selection, training, and qualification requirements for each appropriate function should be established. These should include the minimum requirements for education, experience, skill level, and physical condition, as appropriate.

1.4 QUALITY IMPROVEMENT

Quality improvement is a management process used to improve items, services, products, and processes. Work activities and the management system are subject to continuous improvement through assessment and feedback processes. Item characteristics, process implementation, and other quality-related information shall be reviewed periodically to identify items, services, and processes needing improvement.

Feedback originates from workers, customers, and suppliers. The least desirable form of feedback results from accidents or unplanned events that self-disclose the problem.

1.4.1 General Quality Improvement Requirements

This section defines the management responsibility for building a culture in which continuous improvement is a fundamental and integral part of the organization's mission. ORD and affected organizations establish and implement processes to detect and prevent conditions adverse to quality and to ensure continuous improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected.

1.4.2 Identification of Conditions Adverse to Quality

Personnel are responsible for identifying conditions adverse to quality and should be encouraged by management to suggest improvements. Managers shall foster a "no-fault" attitude to encourage the identification of nonconforming items and processes.

Conditions adverse to quality shall be identified, documented, and reported to the appropriate levels of management responsible for the conditions, to the organization responsible for tracking, and if applicable, to the organization responsible for initiating Lessons Learned.

Documentation shall clearly identify and describe the characteristics that do not conform to specified criteria. A condition adverse to quality shall be identified whenever an AQAP requirement or an implementing document requirement is not met.

The extent of corrective action shall be developed in accordance with the level of significance of the condition adverse to quality and may range from taking remedial action to invoking immediate stop work actions.

A. DOE O 414.1B, Attachment 4, describes the process requirements for line managers to effectively perform corrective actions that resolve safety issues from:

   1. Findings identified by the Offices of Independent Oversight and Performance Assurance; Environment, Safety, and Health; and Emergency Management (DOE O 470.2B, *Independent Oversight and Performance Assurance Program*)

   2. Type A accident investigations (DOE O 225.1A, *Accident Investigations*)

   3. Other sources as directed by the Secretary or Deputy Secretary, including cross-cutting issues.

B. The DOE Office of Oversight safety issues shall be tracked through resolution in the DOE Corrective Action Tracking System.

1.5 DOCUMENTS AND RECORDS

1.5.1 General Document and Records Requirements

Documents and records are required to effectively manage, perform, and assess work. Documents and records shall be prepared, reviewed, approved, issued, used, and maintained. Documents and records shall identify applicable requirements to indicate that work has been properly specified and accomplished. Responsible managers shall identify any documents and records that must be developed and controlled in accordance with applicable records management practices and commit the resources necessary to meet the document and record requirements.

1.5.2 Documents and Records Management System

A. Documents and records are compiled into a records management system that ensures that appropriate records are legible, maintained, and are retrievable. The system shall include provisions for record retention, protection, preservation, change, legibility, traceability, accountability, and retrievability. While in storage, records shall be protected from damage, loss, and deterioration. The hardware and software required to ensure retrievability and usability of archived records should be maintained.

B. The records management system shall provide schedules for records retention and disposition in accordance with DOE and other Federal requirements. The indexing system shall include record retention times and the location of the record within the records system.

2.0 PERFORMANCE REQUIREMENTS

The fundamental elements related to the design, procurement, inspection, test, and control of items and the related administrative activities are described in the following subsections.

2.1 WORK PROCESSES

Qualified personnel shall perform work in accordance with established technical standards and administrative controls, under controlled conditions, using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent damage, loss, or deterioration. The identification and control process shall apply from item manufacture or receipt through delivery, installation, or use. Equipment used for process monitoring or data collection shall be calibrated and maintained.

2.2 DESIGN

Items and processes shall be designed, using sound engineering and scientific principles and the appropriate standards. Applicable requirements and design bases shall be incorporated into the design work and any design changes. Design inputs, outputs, process, verification, interfaces, and changes shall be identified and controlled. Designs shall be verified or validated before they are approved and implemented to ensure the adequacy of the design.

2.2.1 General Design Requirements

A. The design of items, such as structures, systems, and components that involve a higher-than normal level of risk (including those items important to safety that are not governed by other QA programs), shall be subject to more definitive design process control and verification requirements.

B. Designs should provide for appropriate inspection, testing, and maintenance requirements to ensure continuing item reliability and safety. The design should consider the expected use and life expectancy of the items in order to allow appropriate disassembly and disposal requirements to be addressed.

C. Design records shall include documentation of design input, calculations and analyses, engineering reports, design output, design verification activities, and design changes.

D. Design input should be based upon contractual requirements, customer expectations, and safety and shall be technically correct and complete. Design input may include such information as design bases, health and safety considerations, expected life cycle, performance parameters, applicable codes and standards, and reliability requirements.

E. Computer software and software changes used to originate or analyze design solutions during the design process shall be documented and validated for the intended use. Software shall not be used after changes are made until validation of changes is completed and documented. The status of the code validation shall be identified and documented prior to use.

F. The design organization shall perform design analyses and checks to ensure that design output documents meet design input requirements and that any changes have been approved and documented.

G. The completed design shall be recorded in design output documents, such as drawings, specifications, test/inspection plans, maintenance requirements, and reports. As-built drawings and shop drawings shall be maintained after production or construction to show the actual configuration. The administrative interface process shall clearly indicate responsibilities for design output documents including: the mark-up and updating of as-built drawings during the construction and operation phases, and the document control and records management provisions.

H. Technically knowledgeable persons separate from those who performed the design shall perform design verification. Interim verifications may occur at predetermined stages of design development. The technical qualifications of persons performing design verifications should be documented. The extent and number of design verifications should be based on a graded approach and shall depend on the designed product's complexity and importance to safety and project success.

I. Design changes, including field changes and nonconforming items dispositioned "use-as-is" or "repair," shall be documented and controlled by the application of measures commensurate with those applied to the original design. Changes made during the design phase shall be carefully controlled and documented.

2.2.2 Suspect/Counterfeit Items

A. Attachment 1, Suspect/Counterfeit Items Prevention Program, provides guidance to help avoid the procurement and use of suspect/counterfeit items. Additional guidance is also provided for evaluating suspect/counterfeit items that may have been installed.

B. Controls shall be established to develop specifications, evaluate suppliers, plan inspections and/or testing, and inspect items at receipt or prior to installation to prevent the procurement and installation of counterfeit and fraudulent items.

2.3 PROCUREMENT

2.3.1 Procurement General Requirements

A. The procurement process shall ensure that those items and/or services provided by suppliers meet the established requirements and expectations and they perform as specified.

B. The Contractor Requirements Document, Attachment 2 to DOE Order 414.1B, *Quality Assurance*, sets forth contractor requirements to be applied to contractors (e.g., management and integration, management and operation) that are responsible for DOE-owned or -leased facilities and the associated items and services. This includes work that may take place outside the physical boundaries of a DOE facility or work performed by suppliers and subcontractors (such as design, manufacturing, or analytical laboratory services). A graded approach should be used to determine the contractors to whom the requirements will apply. Contractor compliance with the Contractor Requirements Document will be required to the extent identified in the contract documents.

2.3.2 Supplier Qualification

A. Potential suppliers should be identified early in the design and procurement process in order to determine their capabilities. Prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements.

B. A qualified/approved suppliers list should be developed to aid future purchase of spare parts or similar replacement items.

2.3.3 Supplier Performance Monitoring

The qualified supplier's performance should be evaluated periodically during the life of the contract to confirm continuing capabilities. The purchaser should establish measures to interface with the supplier and to verify the supplier's performance.

2.3.4 Inspection

A. The procurement process shall provide for the identification of inspections and tests. Requirements for inspections and tests shall be obtained from the design documents. Inspections shall be adequate to ensure conformance with purchase requirements, including verification that the specified documentation has been provided by the supplier.

B. Critical or important acceptance parameters and other requirements, such as inspection and test equipment or the requirements for qualified inspection and test personnel, shall be specified in the design documentation. In addition, the risks associated with the possibility of obtaining suspect/counterfeit items (see Attachment 1) should be evaluated and, if appropriate, measures implemented to identify them. DOE G 440.1-6, *Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management* provides additional guidance on this subject.

2.3.5 Supplier Documentation

Supplier-generated documents, specified in procurement documents, should be reviewed, validated, and accepted through the procurement system and controlled and processed by the end-user organization according to the provisions of Subsection 1.5, Documents and Records. These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, nonconformances, corrective actions, approved changes, waivers, and other documentation.

2.3.6 Suspect/Counterfeit Items

The selection of suppliers and the purchase of commercial-grade materials should be evaluated to prevent the procurement of suspect/counterfeit items and to detect them before they are released for use. Information in Attachment 1 should be used to minimize the possibility of procuring suspect/counterfeit items.

2.4 INSPECTION AND ACCEPTANCE TESTING

A. Inspections and tests are accomplished to verify that physical and functional aspects of items and services meet requirements specified in engineering and procurement documents and are fit for the intended use. Inspections and tests should be identified early in the design process and specified in the design output documents.

B. Inspection and test planning shall be performed. Appropriate sections of approved codes or standards may be used for acceptance requirements and inspection/test methods.

C. Specified items, services, and processes are inspected and tested using established acceptance and performance criteria. Inspection and test equipment shall be calibrated and maintained.

D. Inspection and test records should, at a minimum, identify:

1. Item tested
2. Date of test
3. Tester or data recorder
4. Observations
5. Results and acceptability
6. Action taken concerning any noted quality problems.

3.0 ASSESSMENT REQUIREMENTS

The fundamental elements related to the performance of Management Assessments, Self-Assessments, and Independent Assessments of activities and items are described in the following sub-sections.

3.1 ASSESSMENTS

Work shall be performed in accordance with established technical standards and administrative controls, under controlled conditions, using approved instructions, procedures, or by other means. Assessments are performed to help assure that work activities and processes are effective and performed in accordance with applicable controls and that requirements are being met.

3.1.1 Assessment Scheduling

Assessments should be scheduled at a frequency commensurate with the status and importance of the work. Regularly scheduled assessments should be supplemented, as required, by additional assessments of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.

3.1.2 Assessment Planning

The assessing organization should develop and document an assessment plan for each scheduled assessment of major scope (a documented assessment plan is not required for limited scope assessments). The planning level will vary depending on the scope, breadth, and the complexity of the process being assessed. Assessment plans should:

A. Identify the scope, based on the evaluation of implementing documents, pre-established expectations, activities and items to be assessed, and the results of previous internal and external audits and surveillances

B. Identify the assessment criteria based on the requirements and expectations

C. Identify the document checklists to be used in the performance of the assessment.

3.1.3 Assessment Performance

Assessment performance includes the following activities:

A. Elements that have been selected for assessment shall be evaluated against specified requirements

B. Assessment methods may include direct observation of the work activity, worker interviews, review of the associated documentation, or the observation of drills or exercises, as appropriate to the assessment scope

C. Assessment results shall be documented by the team and reported to the management having responsibility for the work assessed and the next higher level of management, and the Self-Assessment Program Manager

D. Conditions adverse to quality and nonconforming items shall be documented and corrected in accordance with approved procedures.

3.1.4 Assessment Reporting

Assessment reports shall be prepared, approved, and distributed to the senior management of the organization being assessed and the organization responsible for initiating Lessons Learned.

3.2 MANAGEMENT ASSESSMENT

Managers at every level should periodically assess the performance of their organization to determine the effectiveness of activities supporting AQAP provisions that enable the organization to meet customer requirements and expectations. This assessment should emphasize the use of human and material resources to achieve organizational goals and objectives.

3.2.1 General Management Assessment Requirements

A. Management assessments shall be planned to address appropriate areas of the manager's responsibility.

B. The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting both customer requirements and strategic goals.

C. Management assessments should focus on the identification and resolution of both singular and systemic and management issues and problems that may prevent

customer requirements and expectations from being met. Strengths and weaknesses affecting the achievement of objectives should be identified so that meaningful action can be taken to improve quality.

D. Processes being assessed should include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, feedback systems (for continuous improvement), integration of management systems (e.g., safety, quality, project), and supervisory oversight and support.

E. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve processes.

F. Those areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis.

3.2.2 Process

Direct observation of work is an effective, preferred assessment method that will make the manager aware of interactions at a work location. Other methods that are useful when combined with observation include worker and customer interviews, safety and performance documentation reviews, and drills or exercises.

3.2.3 Results

Management assessment results shall be documented and used as input to the organization's improvement process.

3.3 INDEPENDENT ASSESSMENT

3.3.1 General Requirements

A. Planned and periodic independent assessments shall be conducted in accordance with approved procedures to measure item and service quality, process effectiveness, and to promote improvement.

B. The individual or team performing assessments shall have sufficient authority and freedom from line management and the activities being assessed to carry out the assigned responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable of the items and activities being assessed.

C. Independent assessments conducted by ORD and contractor line organizations support implementation of DOE Policy P 450.5, *Line Environment, Safety, And Health Oversight*. ORD line organizations should apply the results of independent assessments to their work and the work of their contractors. Contractor line organizations should apply the independent assessments to their work and the work of their subcontractors.

D. Separately, the Secretary of Energy has established the Office of Oversight to conduct independent assessments of DOE and contractor safety performance. DOE and contractor organizations should not consider the Office of Oversight function as satisfying the QA rule/order requirements for independent assessment.

E. DOE has developed expanded guidance on this subject that should be consulted for planning and performing independent assessment activities (DOE G 414.1-1, *Management Assessment and Independent Assessment Guide*).

3.3.2 Independent Assessment Process

A. Independent assessments shall be planned to ensure that the assessment is value-added, risk-based, comprehensive, and provides the least amount of disruption to the work process being assessed.

B. The type and frequency of independent assessments should be based on the status, complexity, risk, and importance of the activities or processes being assessed. The criteria used for assessments should describe acceptable work performance and should promote improvement of the process or activity. Assessments should also address management processes that affect work performance, such as planning, program support, and training.

C. Independent assessments may include methods such as monitoring operations, inspections, peer and technical reviews, audits, surveillances, customer interviews, or a combination.

D. The independent assessment process should include verification of the adequacy of corrective actions, including actions identified to preclude recurrence or to otherwise improve performance.

3.3.3 Assessment Results

A. Documented assessment results should be presented to the organization that was assessed and provided to the appropriate levels of management for review.

B. Strengths and weaknesses affecting the quality of process outputs should be identified so that managers can take meaningful action to improve quality.

C. Managers should evaluate the assessment results to identify improvement actions and determine whether similar quality problems may exist elsewhere in the organization.

D. Managers should track improvement actions, through the corrective action program, until a resolution has been implemented and verified as completed.

ATTACHMENT 1

SUSPECT/COUNTERFEIT ITEMS PREVENTION PROGRAM

A suspect/counterfeit items (S/CI) prevention program must be developed and implemented as a part of the quality assurance program for each DOE and contractor, commensurate with the facility or activity hazards and mission impact. The Office of Environment, Safety and Health manages a DOE-wide S/CI prevention program as a service to DOE and contractors that provides for the collection, analysis, and dissemination of S/CI information; notifying Secretarial Officers when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and tracking and reporting the status of corrective actions. This service does not relieve ORD and contractors from complying with the following requirements for the scope of their work.

SUPPLEMENTAL QUALITY MANAGEMENT SYSTEM REQUIREMENTS

The contractor Quality Assurance Program (QAP) must be developed in accordance with the applicable requirements of this AQAP. The provisions of the QAP must be applied when identifying and analyzing SC/Is, removing them, and preventing SC/Is from being supplied to DOE/National Nuclear Security Administration and its contractors. The QAP must address the following S/CI preventative measures:

A. Preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls

B. Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs)

C. Identifying and disposing of S/CIs on site

D. Permitting the use an S/CI only when it has been found acceptable through engineering analysis and formal disposition process

E. Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using available sources that may include:

1. Government Industry Data Exchange Program
2. The Institute of Nuclear Power Operators
3. The DOE Occurrence Reporting and Processing System
4. The U.S. Nuclear Regulatory Commission data.

WORK PROCESS CONTROLS

Controls for work processes must be developed and implemented using S/CI information provided by the Office of Environment, Safety and Health and must include the following elements:

A. Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment

B. Procurement processes that prevent introduction of S/CIs by:

1. Identifying technical and QA requirements in procurement specifications

2. Accepting only those items that comply with the procurement specifications, including consensus standards, and commonly accepted industry practices

3. Inspecting inventory and storage areas to identify, control, and disposition S/CIs.

C. Inspection, identification, evaluation, and disposition of S/CIs installed in systems and other applications that create potential hazards

D. Engineering evaluations and dispositions of S/CIs installed in safety systems or in applications that create potential hazards must consider potential risks to the public and worker and the cost/benefit impact and the schedule for replacement (if required)

E. Ensuring that S/CIs identified in non-safety systems during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications

F. Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs to determine whether to retain them for criminal investigation or litigation

G. Testing procured or installed S/CIs, as necessary, using approved engineering test methods

H. Reporting S/CIs to responsible program offices; the Office of Environment, Safety and Health; and the IG in accordance with DOE O 231.1A, *Environment, Safety, and Health Reporting* and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*

I. Conducting trend analysis and issuing Lessons Learned for use in improving the S/CI prevention program.